

Application Number	78A 101716657
Filing Date	November 20, 2003
First Named Inventor	Joseph V. Boykin, Jr.
Art Unit	78A 1653
Examiner Name	78A LEARY, L
Attorney Docket Number	004629.00024

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Sheet 2 of 5

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Application Number	10/716,657
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First Named Inventor	Joseph V. Boykin, Jr.
Group Art Unit	TEA 1655
Examiner Name	TEA LEARY, L
Attorney Docket Number	004629.00024

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
LL		Peter LIBBY, "Atherosclerosis: The New View" Scientific American, May 2002, pp. 47-55.	
LL		Joseph V. BOYKIN, JR., "Letter to the Editor", Wound Repair and Regeneration, International Journal of Tissue Repair and Regeneration, September-October 2001, pp. 391-392.	
LL		E.B. JUDE, et al., "The role of nitric oxide synthase isoforms and arginase in the pathogenesis of diabetic foot ulcers: possible modulatory effects by transforming growth factor beta 1", Diabetologia (1999), Vol. 42, pp. 748-757.	
LL		Stephen THOM, et al., "Stimulation of perivascular nitric oxide synthesis by oxygen", Am J Physiol Heart Circ Physiol; www.ajpheart.org, December 27, 2002, pp. H1230-H1239.	
LL		Joseph V. BOYKIN, JR., "The Nitric Oxide Connection: Hyperbaric Oxygen Therapy, Becaplermin, and Diabetic Ulcer Management", Journal for Prevention and Healing Advances in Wound Care; www.woundcarenet.com, July/August 2000.	
LL		NAVAS, et al., "Inactivation of Factor C by Dimethyl Sulfoxide Inhibits Coagulation of the Carcinoscopus Amoebocyte Lysate", Biochemistry International, Vol. 21, No. 5, August 1990, pp. 805-813.	
LL		Joseph V. BOYKIN, JR., "Hyperbaric Oxygen Therapy: A Physiological Approach to Selected Problem Wound Healing", WOUNDS; , Vol. 8, No. 6, November/December 1996, pp. 183-198.	
LL		Eman EL-SALAHY, et al., "New scope in angiogenesis: Role of vascular endothelial growth factor (VEGF), NO, lipid peroxidation, and vitamin E in the pathophysiology of pre-eclampsia among Egyptian females", Clinical Biochemistry 34, 2001, pp. 323-329.	
LL		Sharon O'BYRNE, et al., "Nitric Oxide Synthesis and Isoprostane Production in Subjects With Type 1 Diabetes and Normal Urinary Albumin Excretion", Diabetes, Vol. 49, May 2000, pp. 857-862.	
LL		Jeffrey BULGRIN, et al., "Nitric Oxide Synthesis is Suppressed in Steroid-Impaired and Diabetic Wounds", WOUNDS: A Compendium of Clinical Research and Practice, Vol. 7, No. 2, March/April 1995, pp. 48-57	
LL		E.P. COHEN, et al., "The Role of Nitric Oxide in Radiation Nephropathy", Archives of Physiology and Biochemistry, Vol. 104, No. 2, 1998, pp. 200-206.	

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LE		Michael SCHAFFER, et al., "Nitric Oxide Regulates Wound Healing", Journal of Surgical Research 63, 1998, pp. 237-240.	
LE		G. A. C. MURRELL, et al., "Modulation of tendon healing by nitric oxide", Inflammation Research 46, 1997, pp. 19-27.	
LE		Michael SCHAFFER, et al., "Nitric Oxide Metabolism in Wounds", Journal of Surgical Research 71, 1997, pp. 25-31.	
LE		Stephen WILLIAMS, et al., "Impaired Nitric Oxide-Mediated Vasodilation in Patients With Non-Insulin-Dependent Diabetes Mellitus", JACC, Vol. 27, No. 3, March 1996, pp. 567-574.	
LE		Yasuhiro NOZAKI, et al., "Nitric oxide as an inflammatory mediator of radiation pneumonitis in rats", The American Physiological Society, 1997, pp. L651-L658.	
LE		Marianna HUSZKA, et al., "The Association of Reduced Endothelium Derived Relaxing Factor-No Production With Endothelial Damage and Increased in Vivo Platelet Activation in Patients with Diabetes Mellitus", Thrombosis Research, Vol. 38, No. 2, 1997, pp. 173-180.	
LE		Frank THORNTON, et al., "Healing in the Gastrointestinal Tract", Wound Healing, Vol. 77, No. 3, June 1977, pp. 549-573.	
LE		Anders ULLAND, et al., "Altered Wound Arginine Metabolism by Corticosterone and Teinoic Acid", Journal of Surgical Research 70, 1997, pp. 84-88.	
LE		Michael SCHAFFER, et al., "Diabetes-impaired healing and reduced wound nitric oxide synthesis: A possible pathophysiologic correlation", Surgery, Vol. 121, 1997, pp. 513-519.	
LE		Maria CATALANO, et al., "Basal nitric oxide production is not reduced in patients with noninsulin-dependent diabetes mellitus", Vascular Medicine, Vol. 2, 1997, pp. 302-305.	
LE		Michael SCHAFFER, et al., "Abstract [Nitric oxide is decreased in diabetic wound healing]", Langebecks Arch Chir Suppl. Kongressbd, Vol. 114, 1997, pp. 519-521.	

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Sheet 4 of 5	Attorney Docket Number	004629.00024	

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LL		Liangwen SONG, et al., "The Protective Action of Taurine and L-Arginine in Radiation Pulmonary Fibrosis", Journal of Environmental Pathology, Toxicology and Oncology, Vol. 17, No. 2, 1998, pp. 151-157.	
LL		D. CLARENCON, et al., "Voltametric measurement of blood nitric oxide in irradiated rats", Int. J. Radiat. Biol., Vol. 75, No. 2, 1999, pp. 201-208.	
LL		Alexander MINCHENKO, et al., "Endothelin-1, Endothelin Receptors and eNOS Gene Transcription in Vital Organs During Traumatic Shock in Rats", Endothelium, Vol. 6, No. 4, 1999, pp. 303-314.	
LL		Michael SCHAFER, et al., "Lymphocyte function in wound healing and following injury", British Journal of Surgery, Vol. 85, 1998, pp. 444-460.	
LL		Mary BLISS, "Hyperaemia", Journal of Tissue Viability, Vol. 8, No. 4, 1998, pp. 4-13.	
LL		Chris BAYLIS, et al., "Measurement of nitrite and nitrate levels in plasma and urine - what does this measure tell us about the activity of the endogenous nitric oxide system?", Nephrology & Hypertension, Vol. 5, No. 29, 1998, pp. 59-62.	
LL		Aristidis VEVES, et al., "Endothelial Dysfunction and the Expression of Endothelial Nitric Oxide Synthetase in Diabetic Neuropathy, Vascular Disease, and Foot Ulceration", Diabetes, Vol. 47, March 1998, pp. 457-463.	
LL		Tsuneki SUGIHARA, et al., "Preferential Impairment of Nitric Oxide-Mediated Endothelium-Dependent Relaxation in Human Cervical Arteries After Irradiation", American Heart Association, Inc.; www.circulationaha.org, 1999, pp. 635-641.	
LL		William DODSON III, et al., "3-Nitrotyrosine Predicts Healing in Chronic Diabetic Foot Wounds Treated with Hyperbaric Oxygen", Clinical Research, Vol. 11, No. 6, November/December 1999, pp. 129-136.	
LL		David EFRON, et al., "Expression and Function of Inducible Nitric Oxide Synthase During Rat Colon Anastomotic Healing", J. Gastrointest Surg., Vol. 3, 1999, pp. 592-601.	
LL		Hang Ping SHI, et al., "Supplemental dietary arginine enhances wound healing in normal but not inducible nitric oxide synthase knockout mice", Surgery, Vol. 128, 2000, pp. 374-378.	

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LL		Bary CAMPBELL, et al., "Vascular endothelial growth factor attenuates trauma-induced injury in rats", British Journal of Pharmacology, Vol. 129, 2000, pp. 71-76.	
LE		Thomas MISKO, et al., "A Fluorometric Assay for the Measurement of Nitrite in Biological Samples", Analytical Biochemistry, Vol. 214, 1993, pp. 11-16.	
LL		Mary GILLIAM, et al., "A spectrophotometric Assay for Nitrate Using NADPH Oxidation by Aspergillus Nitrate Reductase", Analytical Biochemistry, Vol. 212, 1993, pp. 359-365.	
LE		Jeffrey BULGRIN, et al., "Arginine-free diet suppresses nitric oxide production in wounds", J. Nutr.Biochem, Vol. 4, October 1993, pp. 588-593.	
LL		Joseph BOYKIN, JR., et al., "Diabetes-Impaired Wound Healing Predicted by Urinary Nitrate Assay: A Preliminary, Retrospective Study", WOUNDS: A Compendium of Clinical Research and Practice, Vol. 11, No. 3, May/June 1999, pp. 62-69.	

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